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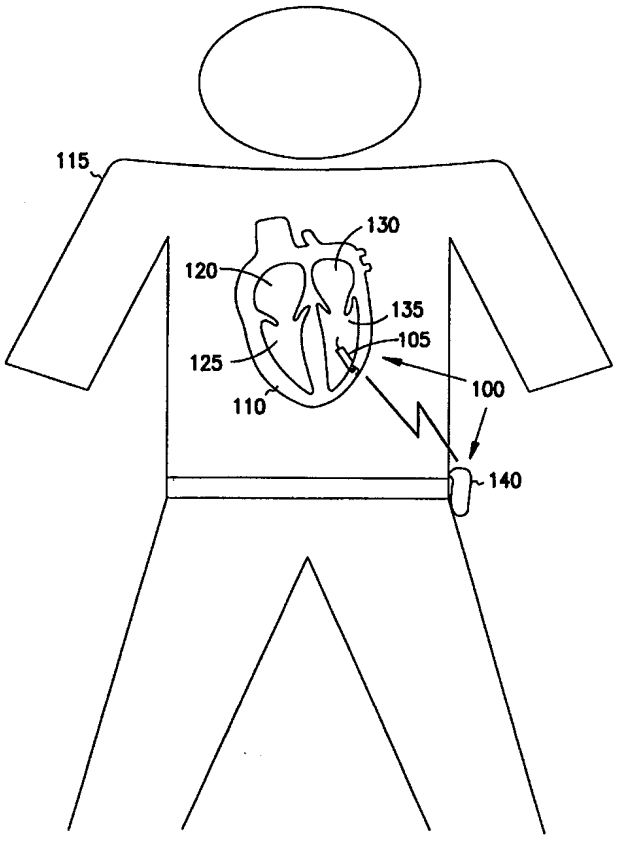
(54) Title: IMPLANTABLE SENSOR WITH WIRELESS COMMUNICATION

(57) Abstract

An implantable sensor device, such as a pressure monitor, is implanted in the left ventricle (LV), in other heart chambers, or elsewhere, from which it wirelessly communicates pressure information to a remote communication device. The sensor device can be implanted using a placement catheter, an endoscope, or a laparoscope. The device can be secured entirely within the LV or heart wall, such as by using a corkscrew, a helical anchor, a harpoon, a threaded member, a hook, a barb, a fastener, a suture, or a mesh or coating for receiving fibrous tissue growth. The implantable sensor device provides less invasive chronic measurements of left ventricular blood pressure or other physical parameters. The wireless communication techniques include radio–telemetry, inductive coupling, passive transponders, and using the body as a conductor (referred to as "intracorporeal conductive communication" or "personal area network"). Data from the receiver is downloadable into a computer for analysis or display.



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IMPLANTABLE SENSOR WITH WIRELESS COMMUNICATION

Field of the Invention

This invention relates generally to an implantable sensor with wireless communication, and particularly, but not by way of limitation, to physiological monitoring of pressure or other parameters in humans and animals using a monitor that is implantable within a heart chamber or elsewhere and is capable of wireless communication of sensor information therefrom.

Background

The monitoring of fluid pressure within a body organ provides an important tool for medical research and clinical diagnosis. For example, hydrocephalus and head injuries can cause body fluids to build up within the brain. The resulting fluid pressure buildup can result in death or serious brain damage. In another example, urinary dysfunction can cause fluid pressure to build up in the bladder. In a further example, intrapleural pressure measurements can be used to monitor the respiration of infants who have been identified as being at risk for sudden infant death syndrome.

Blood pressure measurements are particularly important for medical research and diagnosis for a variety of reasons. Such measurements provide researchers with insight into the physiology and functioning of the heart. Blood pressure measurements also provide researchers with useful information regarding the safety and efficacy of pharmaceuticals and the toxicity of chemicals. By transducing blood pressure into a signal waveform, a variety of useful parameters can be extracted. These parameters provide valuable information for the diagnosis of heart disease. Left ventricular (LV) blood pressures measurements are particularly important because the left ventricle chamber of the heart pumps blood to the systemic circulatory system, that is, throughout the rest of the body.

Common parameters extracted from left ventricular blood pressure waveforms include peak systolic pressure (the high pressure peak resulting from a contraction of the left ventricle chamber of the heart), end diastolic pressure (the low pressure valley resulting from expansion of the left ventricle), and

maximum dP/dt (a peak value of how fast the pressure (P) changes with time (t) during a contraction of the left ventricle). These blood pressure measurements provide helpful diagnostic information to the physician.

For example, maximum dP/dt provides a measure of the work that is being done by the heart. For certain conditions, such as congestive heart failure (CHF), it is desired to reduce the work load on the heart. The treating physician can determine how effective a therapy is by determining if the treatment regimen has indeed reduced the work load on the heart, as indicated by the maximum dP/dt signal extracted from the left ventricular blood pressure waveform. Measurement of left ventricular blood pressure is also useful for titrating new drugs for treating heart disease, that is, determining the desired dosage or concentration of a new drug. Titrating new drugs requires information on how these drugs are affecting the heart.

For example, beta adrenergic blocking drugs are often effective at treating arrhythmias and improving patient hemodynamics. However, such drugs are difficult to titrate. Because left ventricular blood pressure parameters, such as maximum dP/dt, provide information on how the heart is functioning, monitoring these parameters allows a physician to more easily determine the most appropriate dose of the drug for treating the patient. The maximum dP/dt signal, if available, could also be used as a feedback mechanism in a system that automatically delivers therapy to adjust the work load of the heart. The delivery of therapy is automatically adjusted based on the work load of the heart, as indicated by the maximum dP/dt signal.

In another example, left ventricular blood pressure provides useful information for controlling a cardiac rhythm management system. Cardiac rhythm management systems include, among other things, pacemakers, or pacers. Pacers deliver timed sequences of low energy electrical stimuli, called pace pulses, to the heart. Heart contractions are initiated in response to such pace pulses. By properly timing the delivery of pace pulses, the heart can be induced to contract in proper rhythm, greatly improving its efficiency as a pump. Pacers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slowly, or irregularly. Cardiac rhythm management systems also include cardioverters or defibrillators that are capable of delivering higher energy

electrical stimuli to the heart. Defibrillators are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly. Such too-fast heart rhythms also cause diminished blood circulation because the heart isn't allowed sufficient time to fill with blood before contracting to expel the blood. Such pumping by the heart is inefficient. A defibrillator is capable of delivering an high energy electrical stimulus that is sometimes referred to as a countershock. The countershock interrupts the tachyarrhythmia, allowing the heart to reestablish a normal rhythm for the efficient pumping of blood. In addition to pacers, cardiac rhythm management systems also include, among other things, pacer/defibrillators that combine the functions of pacers and defibrillators, drug delivery devices, and any other systems or devices for diagnosing or treating cardiac arrhythmias.

One example of using a cardiac rhythm management device to control heart rate in proportion to left ventricular blood pressure is described in Mehra U.S. Patent No. 5,129,394. The '394 patent, however, does not disclose sensing actual left ventricular blood pressure. Instead, it discloses a pressure sensor located in the coronary vein. The coronary vein extends from the right atrium through the heart tissue near the left ventricle. Because of its small size, the coronary vein is difficult to access for inserting a pressure sensor. Moreover, blood pressure sensing in the coronary vein provides only an indirect approximation of the actual left ventricular blood pressure.

Other existing techniques for monitoring left ventricular blood pressure also have drawbacks. One technique of measuring left ventricular blood pressure is described in Brockway et al. U.S. Patent No. 4,846,191, which is assigned to the assignee of the present application. The '191 patent describes a pressure sensor that is implanted in the abdomen of a laboratory animal. The pressure sensor is connected to an organ, such as the heart or the brain, via a fluid-filled pressure transmitting catheter (PTC). One limitation of this device is that it requires invasive access to the organ in which fluid pressure is to be monitored.

For example, in monitoring left ventricular pressure, one surgical technique for using the device described in the '191 patent involves performing a highly invasive laparotomy procedure. In this procedure, the pressure

transmitting catheter is passed through an incision in the diaphragm and an incision into the apex (bottom tip) of the heart. The high blood pressure in the left ventricle further increases the risk of making such incisions directly into the left ventricle. This procedure typically requires a two week recovery period for the laboratory animal. Moreover, because catheterization of the apex involves significant risks, this technique would likely be considered too invasive for human use.

Alternatively, an incision may be made into the aorta, which is the primary artery carrying blood from the left ventricle to the rest of the body. The pressure transmitting catheter is then passed into the aortic incision for measuring blood pressure in the aorta. Aortic incisions are also problematic because of the high blood pressure in the arterial circulatory system. Moreover, measuring blood pressure in the aorta does not provide a direct measurement of blood pressure in the left ventricle; such information is unavailable, for example, when the aortic valve is closed. Alternatively, the pressure transmitting catheter could be passed through the aortic valve into the left ventricle. However, leaving the pressure transmitting catheter extending through the aortic valve for a long period of time risks damage to the aortic valve as a result of the high blood pressure in the left ventricle. Thus, this procedure is also likely unsuitable for human use, particularly for chronic left ventricular blood pressure monitoring, i.e., monitoring over an extended period of time.

Another technique for measuring left ventricular blood pressure is described in Pohndorf et al. U.S. Patent No. 5,353,800. A distal end of a pressure sensing lead is transvenously introduced into the right ventricle of the patient's heart. A hollow needle at the distal end of the lead is punched through the ventricular septum, that is, through the wall separating the right and left ventricles. This provides access to the left ventricle for sensing pressure gradients that are communicated through the hollow needle to a pressure sensor that is outside of the left ventricle. Because this procedure involves invasively forming an opening in the septum, it creates significant risks for human cardiac patients who are likely already very sick and vulnerable to such risks.

A further technique for measuring left ventricular blood pressure uses a pressure sensing catheter, such as a "Millar catheter," available from Millar

Instruments, Inc., of Houston, TX. The pressure sensing catheter is passed through the left atrium and through the mitral valve (which separates the left atrium and left ventricle) into the left ventricle. As discussed above, however, high blood pressures exist in the left ventricle, which would likely result in damage to the mitral valve if the catheter were left interposed in the mitral valve for a long period of time. As a result, if a sequence of successive measurements is to be obtained over a long period of time, the patient must undergo recatheterization for each measurement. However, catheterization itself involves risk, discomfort, and expense, making multiple catheterizations of the patient very undesirable.

In summary, present techniques for measuring left ventricular pressure are too invasive for human use and unsuitable for use over an extended period of time. Physicians and researchers need less invasive techniques for chronic measurement of left ventricular blood pressure, both for diagnosing heart conditions and for determining whether therapy delivered to the heart is adequate for effectively treating the patient's symptoms.

Summary

The present system provides, among other things, a less invasive implantable sensor device capable of wirelessly communicating sensor information. The sensor is implantable in a heart chamber, in other body organs and body cavities, and elsewhere within a living organism. One example includes a blood pressure monitoring device that is suitable for use over an extended period of time in the left ventricle for wirelessly communicating blood pressure information therefrom. This provides less invasive chronic pressure measurements in the left ventricle. As a result, the risk of obtaining such important measurements is reduced. This enables a physician to more accurately diagnose and treat serious heart conditions. It also enables a biomedical researcher to monitor sensor signals in animal research studies.

In one example, the wirelessly communicated left ventricular blood pressure information is used to control the delivery of therapy by a cardiac rhythm management device. In another example, the present system advantageously allows a physician to obtain a sequence of left ventricular blood pressure measurements over a long period of time. By contrast, using a pressure

sensing catheter for obtaining such measurements over a long period of time risks damaging heart valves because of the high blood pressures that exist in the left ventricle. Because the present system allows long term monitoring, it can be used, for example, in assessing circadian variations in physiological data over a period of time. Such information is potentially valuable in diagnosing and treating patients. *See, e.g.,* Brian P. Brockway, Perry A. Mills, and Sylvia H. Azar, "A New Method For Continuous Chronic Measurement and Recording of Blood Pressure, Heart Rate, and Activity in the Rat via Radio-Telemetry," Clinical and Experimental Hypertension - Theory and Practice, A13(5), pp. 885-895 (1991), which is incorporated herein by reference in its entirety.

Certain particular embodiments of the invention are summarized below, by way of illustrative example, but not by way of limitation. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

One aspect of the invention provides an apparatus for sensing a parameter in a heart chamber in a heart in a living organism. The apparatus includes a sensor and a wireless communication circuit. The sensor is adapted for being disposed in the heart chamber. The sensor provides a sensor signal based on the parameter sensed in the heart chamber. The wireless communication circuit is adapted for being disposed in the heart chamber. The communication circuit is coupled to the sensor and transmits information out of the heart chamber based on the sensor signal. The wireless communication techniques include radio-telemetry, reactive coupling, passive transponders, and intracorporeal conductive communication.

In one embodiment, the sensing apparatus includes a housing carrying the sensor and the communication circuit and at least one stabilizer that is coupled to the housing. Also included in the housing is a battery which, in one embodiment, is recharged by energy received from outside the heart chamber. A receiver, external to the heart chamber, is communicatively coupled to the communication circuit for receiving the information based on the sensor signal. In one embodiment, the receiver is carried by a cardiac rhythm management system, and therapy delivered by the cardiac rhythm management system is adjusted according to information wirelessly received from the sensor device

implanted in the heart chamber. In another embodiment, the receiver is coupled to a computer that analyzes or displays the information from the sensor. In one embodiment, the sensor is a pressure transducer, however, other sensors may also be used.

Another aspect of the invention includes a method of sensing a parameter (e.g., blood pressure) in a heart chamber in a heart in a living organism. A physical manifestation of the parameter in the heart chamber is received at a sensor disposed within the heart chamber, where it is transduced into a sensor signal. Information based on the sensor signal is wirelessly communicated from the heart chamber. A further embodiment includes translumenally disposing the sensor in the heart chamber.

One embodiment of communicating the information includes using a passive transponder. In this technique, energy is received from outside the heart at a passive transponder that is in the heart. The passive transponder is powered from the energy received from outside the heart chamber. Information is transmitted from the heart chamber using the powered passive transponder. In another embodiment, energy received from outside the heart chamber is used to recharge a battery that is located in the heart chamber.

Another embodiment of communicating information includes using intracorporeal conductive communication, which uses the living organism as the conductor. In this technique, a current is conducted through at least a portion of the living organism. A signal that is based on this current is received at a receiver that is outside the heart chamber. In one embodiment, the receiver is carried by an implantable medical device located within the living organism such as, for example, a cardiac rhythm management device. Therapy delivered by the cardiac rhythm management device is adjusted based on the signal received by intracorporeal conductive communication or other wireless communication technique. In another embodiment, the receiver is external to the living organism, and information is stored in a memory in the receiver.

Another aspect of the invention provides a method. The method includes inducing a current between first electrodes implanted in a living organism. The current at the first electrodes is modulated with a data signal. A signal based on

the current is demodulated at second electrodes. In one embodiment, the second electrodes are also implanted in the living organism.

Another aspect of the invention provides a catheter. The catheter includes an elongate member having first and second ends. The first end of the elongate member includes a cavity adapted for carrying an implantable measurement device that includes a wireless communication circuit. The elongate member also includes a lumen extending substantially between the cavity and the second end of the elongate member. An engaging member is carried by the cavity. The engaging member is extendable outwardly from the cavity at the first end of the elongate member. The engaging member is operatively coupled to a manipulator at the second end of the elongate member. The engaging member is adapted for engaging the implantable measurement device. In one embodiment, portions of the elongate member are flexible such that the catheter is adapted for translumenal access to a heart chamber. Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

Brief Description of the Drawings

In the drawings, like numerals describe substantially similar components throughout the several views.

Figure **1** is a schematic diagram illustrating generally one embodiment of portions of a sensor system, such as a pressure monitor system, and an environment in which it is used.

Figure **2** is a schematic diagram illustrating generally an embodiment of certain external portions of the system.

Figure **3A** is a schematic/block diagram illustrating generally one embodiment of a portion of an implantable sensor device, such as an implantable pressure monitor device including a corkscrew stabilizer.

Figure **3B** is a schematic/block diagram illustrating generally one embodiment of an implantable sensor device, such as an implantable pressure monitor device including a harpoon or barbed stabilizer.

Figure **3C** is a schematic/block diagram illustrating generally one embodiment of an implantable sensor device, such as an implantable pressure monitor device including a mesh stabilizer and a corkscrew stabilizer.

Figure **3D** is a schematic/block diagram illustrating generally one embodiment of an implantable sensor device, such as an implantable pressure monitor device including a deformable stabilizer.

Figure **4** is a schematic diagram illustrating generally one embodiment of the present system using wireless communication, such as intracorporeal conductive communication, between an implanted medical device, such as cardiac rhythm management system, and an external remote receiver.

Figure **5** is a schematic diagram illustrating generally one embodiment of the present system using wireless communication, such as intracorporeal conductive communication, between an implanted sensor device and an implanted remote receiver that is carried by an implanted medical device such as by cardiac rhythm management system

Figure **6** is a cross-sectional schematic diagram illustrating generally one embodiment of a placement catheter for implanting a sensor device, such as an implantable pressure monitor device.

Figure **7** is a schematic diagram illustrating another embodiment of an implantable sensor device, such as a pressure monitor, having a housing that is substantially implanted within tissue, such as the interior wall of a heart chamber.

Figure **8** is a schematic diagram illustrating generally another embodiment of a sensor device for implantation substantially within tissue and having a substantially flexible anchor.

Figure **9** is a schematic diagram illustrating generally another embodiment of a sensor device for implantation substantially within tissue and having a substantially rigid anchor.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and

scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents. In the drawings, like numerals describe substantially similar components throughout the several views.

This document describes, among other things, an implantable sensor, such as a pressure monitor. The sensor device is implanted in a heart chamber (or elsewhere) and wirelessly communicates information therefrom. In one embodiment, the sensor device is capable of providing less invasive chronic measurements of pressure, such as, by way of example, but not by way of limitation, measurements of blood pressure in the left ventricle of the heart. The implantable pressure monitor reduces the risk of obtaining such important measurements, enabling a physician to more accurately diagnose and treat serious heart conditions.

System Overview

Figure **1** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of portions of a sensor system, such as pressure monitor system **100**, and one environment in which system **100** is used. In Figure **1**, system **100** includes a sensor device, such as an implantable pressure monitor device **105**. Device **105** is introduced into a living organism, such as in a heart chamber or other organ or body cavity. Miniature implantable device **105** is capable of measuring internal body pressure, such as in humans or animals. Aspects of one embodiment of device **105** and its operation are described in Brockway et al. U.S. Patent No. 4,846,191 entitled "Device For Chronic Measurement of Internal Body Pressure," which is assigned to the assignee of the present application, and which is incorporated herein by reference in its entirety.

In Figure **1**, device **105** is implanted in a heart **110** of a human patient **115**. Heart **110** includes several heart chambers, such as a right atrium **120**, a right ventricle **125**, a left atrium **130**, and a left ventricle **135**. In this particular example, device **105** is implanted, using a placement catheter, inside left ventricle **135** where it is stabilized, such as by securing the device **105** to an interior wall of left ventricle **135**. However, in other embodiments, device **105** is

implanted in one of the right atrium **120**, right ventricle **125**, left atrium **130**, or within other organs or body cavities. Device **105** can be introduced into the body translumenally (e.g., transvenously or transarterially), endoscopically, laparoscopically, or otherwise (e.g., during open heart surgery).

In this embodiment, system **100** also includes an implantable or external receiver **140** or other receiver, transceiver, transponder, or communication device. Device **105** wirelessly communicates pressure information from the organ in which device **105** is located, such as by using radio telemetry or any other wireless communication technique. In Figure **1**, left ventricular blood pressure information is communicated by device **105** and received by an external receiver **140** worn by the patient. In one embodiment, receiver **140** includes a memory or recording device for storing the pressure information received from device **105**. In a further embodiment, receiver **140** includes a real time clock for time-stamping the pressure information with the time at which the information is received at receiver **140**.

Figure **2** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another embodiment of portions of system **100**. In Figure **2**, pressure information that was stored in the memory or recording device of receiver **140** is transferred into computer **200**, such as via an electrical coupling cable **205**, or alternatively via optical communication, or using any other wired or wireless communication technique. In one embodiment, computer **200** includes a processor for performing statistical or other signal processing or analysis of the pressure information. In another embodiment, computer **200** includes a display **202** for allowing the physician or other care giver to review and analyze the pressure data. In one example, display **202** includes diagnostic indicators based on analysis of the pressure data by computer **200**. In a further embodiment, computer **200** includes a memory for archival of raw or processed pressure information. For example, the pressure information can be electronically appended to the patient's medical record in a computer database.

Implantable Pressure Monitor

Figure **3A** is a schematic/block diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of device **105**. In this

embodiment, device **105** includes a housing **300** carrying a sensor, such as pressure transducer **305**, and a communication circuit **310**. Housing **300** is adapted for implantation in a living organism such as a human or animal. In one example, housing **300** is implanted within a body cavity or an organ, such as within a heart chamber (e.g., left ventricle **135**) of heart **110**.

In one embodiment, device **105** includes a stabilizer **312A** extending outward from housing **300** to stabilize or secure device **105** at a particular location in the heart chamber or other organ in which device **105** is implanted. Figure **3A** illustrates a corkscrew stabilizer **312A** which, in one embodiment, includes a solid coiled needle extending longitudinally outward from housing **300**. By rotating device **105**, corkscrew stabilizer **312A** is screwed into the wall of the heart chamber or other organ in which device **105** is disposed, thereby securing device **105** at a particular location in the body. The corkscrew stabilizer **312A** is used with or without one or more barbs. The barbs are located, for example, at a tip distal from device **105**, or at different locations along the helical length of stabilizer **312A**. In one embodiment, the surface of corkscrew stabilizer **312A** is coated or otherwise prepared to promote the growth of fibrotic tissue to reliably secure device **105** to the heart wall or other desired location.

Figure **3B** illustrates generally one embodiment of a harpoon stabilizer **312B**, providing an approximately straight outward extension from housing **300**, and including a barb or hook at its distal tip. Figure **3C** illustrates generally one embodiment of a mesh stabilizer **312C**, extending outward from or integrally formed with housing **300**. Mesh stabilizer **312C** also promotes the ingrowth of adjacent fibrous tissue to assist in securing device **105** at a particular location. Figure **3D** illustrates generally one embodiment of a flexible or expanding deformable stabilizer **312D**. In one embodiment, stabilizer **312D** is made of a flexible, spring-like, or deformable material or a "memory metal." As illustrated in Figure **3D**, stabilizer **312D** maintains a compact shape during implantation, but deforms or expands in profile after device **105** is implanted into the heart chamber or other body cavity. As a result of this deformation or expansion, stabilizer **312D** tends to hold device **105** within the body cavity in which it is implanted. The above-discussed stabilizers **312** can also be used in combination with each other, such as illustrated in Figure **3C**.

Figures **3A - 3D** illustrate particular embodiments of device **105** in which the internal pressure of the organ is provided to pressure transducer **305** via a pressure communication apparatus such as, by way of example, but not by way of limitation, a flexible or rigid pressure transmitting catheter (PTC) **315**. In one embodiment, pressure transmitting catheter **315** senses a pressure at one or more pressure-sensitive mechanisms (e.g., a diaphragm, gel-like cap, or other compliant structure) at its distal tip **320**. Pressure transmitting catheter **315** communicates the pressure, via a bore, shaft, or lumen **325**, to its proximal end **330** that interfaces with transducer **305**. Lumen **325** extends substantially between distal tip **320** and proximal end **330** of pressure transmitting catheter **315**. In one embodiment, lumen **325** is filled with a pressure-transmitting medium, such as a fluid of any viscosity, a gel-like material, a combination of fluid and gel-like material, or any other flowable medium. In one embodiment, by way of example, but not by way of limitation, distal tip **320** includes a biocompatible and pressure-transmitting gel cap for transmitting substantially steady-state and/or very low frequency pressure variations, and distal tip **320** also includes a thin-wall compliant structure for transmitting pressure variations at higher frequencies. Lumen **325** is filled with a pressure-transmitting fluid retained within lumen **325** by the gel cap. The gel cap also prevents body fluids from entering lumen **325**. Similarly, in one embodiment, proximal end **330** includes one or more pressure-transmitting mechanisms (e.g., a diaphragm, gel-like cap, or other compliant structure), which also retains the pressure-transmitting fluid in lumen **325**. Although one embodiment of device **105** includes pressure transmitting catheter **315**, the technique of communicating pressure to pressure transducer **305** is not limited to using pressure transmitting catheter **315**. For example, device **105** alternatively provides a pressure transmitting mechanism that is integrally formed with housing **300** of device **105** rather than extending outwardly therefrom. Other embodiments of device **105** include the use of any other technique of receiving pressure at pressure transducer **305**.

Pressure transducer **305** receives the pressure communicated by pressure transmitting catheter **315**, or by any other pressure communication mechanism, at the interface at its proximal end **330**. In response, pressure transducer **305**

provides an electrical pressure signal that includes pressure information, such as steady-state pressure or variations in pressure. In one embodiment, pressure transducer **305** includes a semiconductor resistive strain gauge, the resistance of which varies according to the pressure communicated by pressure transmitting catheter **315**. Transducer **305** is electrically coupled to communication circuit **310** and provides the electrical pressure signal to communication circuit **310**.

Communication Techniques

Communication circuit **310** wirelessly transmits pressure information from device **105** to remote receiver **140** (or other receiver, transceiver, transponder, or communication device) by radio telemetry or any other wireless data communication technique. In one embodiment, communication circuit **310** includes or is coupled to an antenna for wireless communication. However, the antenna need not be located within communication circuit **310**. In another embodiment, communication circuit **310** also includes signal processing circuits, such as amplification and filtering circuits that process the electrical pressure signal received from pressure transducer **305**, or analog-to-digital conversion circuits, or a microprocessor or other circuit for performing data analysis or data compression. In a further embodiment, communication circuit **310** also includes a memory device for storing the pressure information, other data, or operating parameters of device **105**. In yet another embodiment, communication circuit **310** includes a real-time clock for time-stamping the pressure information.

In one embodiment, at least one of communication circuit **310** or transducer **305** is powered by an internal power source such as a lithium or other suitable battery **335**. In another embodiment, communication circuit **310** is a passive transponder that is not powered by an internal power source. Instead, communication circuit **310** receives energy wirelessly from a remote source, such as an energy source external to the body of the patient in which device **105** is implanted. Communication circuit **310** is powered by the energy that it receives wirelessly from the external source. In another embodiment, battery **335** is rechargeable and device **105** includes an energy reception circuit that is coupled to battery **335**. The energy reception circuit in device **105** wirelessly receives energy from a remote source, such as an energy source that is external to the body of the patient in which device **105** is implanted. The energy that is

received by the energy reception circuit in device **105** is used by the energy reception circuit to recharge battery **335**.

In one example of passive transponder technology, communication circuit **310** includes a first inductance, such as a coil. A second inductance, such as a coil, is placed outside the body, for example, at a location that is close to the site of the implanted device. The first and second inductances are inductively coupled for wireless energy transmission from the external second inductance to the implanted first inductance, and for wireless data communication from the implanted first inductance to the external second inductance. System **100** may incorporate other passive transponder techniques as well.

In one embodiment, communication circuit **310** wirelessly communicates pressure information from device **105** to external remote receiver **140** using an intracorporeal conductive communication device (also referred to as "near-field intrabody communication" or a "personal area network"). In this document, wireless communication refers to any communication technique that does not use a wire or optical fiber. Wireless communication includes either or both of unidirectional and/or bidirectional communication. The unidirectional or bidirectional communication is carried out between any combination of implanted and/or external communication devices. In various embodiments, certain ones of the communication devices are carried by implanted sensor devices (such as an implanted pressure monitor), implanted medical devices (such as an implanted cardiac rhythm management device), and external communication devices for communication therebetween. Wireless communication includes, but is not limited to: radio telemetry, reactive coupling, and intracorporeal conductive communication. In this document, intracorporeal conductive communication refers to any communication technique that uses a living organism (e.g., the body of a human or animal) as a conductor for communicating data. In one embodiment, wireless communication is used to program operating parameters in implanted device **105**.

In one example of an intracorporeal conductive communication device, communication circuit **310** is electrically coupled to electrodes located on housing **300** and insulated from each other. Communication circuit **310** capacitively couples a very low (e.g., less than a stimulation threshold of heart

110) displacement current that is conducted through the body to remote receiver **140**. The current is modulated with a data signal. The data signal includes the pressure information or other data to be wirelessly communicated from the implanted medical device **105**. In this embodiment, the resulting current is detected at remote receiver **140** by electrodes that contact the body of patient **115** during the wireless communication from device **105**. The detected current is demodulated to obtain the pressure information or other data. The use of intracorporeal conductive communication techniques is described in Coppersmith et al. U.S. Patent No. 5,796,827 entitled "System and Method for Near-Field Human-Body Coupling For Encrypted Communication With Identification Cards," and in T.G. Zimmerman, "Personal Area Networks: Near-field intrabody communication," IBM Systems Journal, Vol. 35, No. 3 & 4, 1996, each of which is incorporated herein by reference in its entirety.

In one embodiment, system **100** includes, among other things, communicating information from any implanted medical device to an external remote receiver **140** using intracorporeal conductive communication (i.e., using the body as a conductor). Examples of such implanted medical devices include, but are not limited to: pressure monitors, cardiac pacemakers, defibrillators, drug-delivery devices, and cardiac rhythm management devices.

Figure **4** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of system **100** using either unidirectional or bidirectional intracorporeal conductive communication between an implanted medical device, such as cardiac rhythm management device **400**, and an external remote receiver **140**. This includes, for example, intracorporeal conductive communication of data from electrodes **405A-B** at the cardiac rhythm management device **400** to electrodes **410A-B** at the external remote receiver **140**, as well as programming operating parameters of cardiac rhythm management device **400** based on instructions received via intracorporeal conductive communication from external remote receiver **140**.

Figure **5** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another embodiment of system **100** using either unidirectional or bidirectional intracorporeal conductive communication between electrodes **505A-B** at pressure monitor device **105**, which is implanted

in left ventricle **135**, and electrodes **405A-B** coupled to an implanted remote receiver **140** carried by an implanted medical device, such as by cardiac rhythm management device **400**. In one embodiment, cardiac rhythm management device **400** includes a therapy generator that is coupled to heart **110** through a leadwire. In this embodiment, device **105** senses left ventricular blood pressure and communicates, via intracorporeal conductive communication, left ventricular blood pressure information to cardiac rhythm management device **400** where it is received by implanted receiver **140**. Based on the received pressure information, cardiac rhythm management device **400** adjusts therapy delivered to heart **110**. In one example, cardiac rhythm management device **400** is a pacer or pacer/defibrillator that adjusts the rate of delivering electrical pacing pulses to heart **110** via leadwire **500** based on the left ventricular pressure information received from device **105**. In another example, cardiac rhythm management device **400** is a defibrillator or pacer/defibrillator that delivers antitachyarrhythmia therapy to heart **110** based on the left ventricular pressure information received from device **105**. Similarly, system **100** includes using intracorporeal conductive communication to transmit information to device **105** from another implanted medical device, such as cardiac rhythm management device **400**. Moreover, the embodiments described with respect to Figures **4** and **5** can be combined for communication between any of one or more implanted medical devices, one or more implanted sensor devices such as device **105**, and/or one or more external or implanted remote receivers **140**.

Implantation and Use

Figure **6** is a cross-sectional schematic diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of a placement catheter **600** for implantably disposing device **105** in a heart chamber, such as left ventricle **135**. Catheter **600** includes an at least partially flexible elongate member having a proximal end **600A** that is manipulated by the user. Catheter **600** also includes a distal end **600B** of the elongate member that is inserted in the patient **115**. In one embodiment, the distal end **600B** of catheter **600** includes a cavity **605** carrying at least a portion of device **105**. Cavity **605** is circumferentially encompassed by a sheath **607** that, in one embodiment, is open at distal end **600B** of catheter **600**.

Catheter **600** also includes at least one engaging member, such as plunger **610**. Plunger **610** engages device **105**. In one example, an inner surface of plunger **610** includes protrusions, such as pins **615**, that engage receptacles **620** or other indentations in housing **300** of device **105**. Plunger **610** is controlled at proximal end **600A** of catheter **600** by a manipulator, such as handle **625**. Handle **625** is coupled to plunger **610** by a coupling member **630**, such as one or more rods or cables extending longitudinally within catheter **600**. Plunger **610** is capable of longitudinal motion toward and away from distal end **600B** of catheter **600**, so that device **105** can be advanced from or retracted toward cavity **605**. Plunger **610** is also capable of rotational motion, by manipulating handle **625**, so that corkscrew stabilizer **312A** can be rotatably screwed into tissue such as the heart wall. Pins **615** engage receptacles **620** to ensure that device **105** rotates together with plunger **610**.

In one embodiment, catheter **600** also includes a safety tether **635**, which is looped through an opening or other feature in housing **300** of device **105**. Tether **635** extends longitudinally through catheter **600** toward proximal end **600A**, where the looped tether **635** is knotted or otherwise secured at a tether keep **640** on handle **625** or elsewhere. Tether **635** secures device **105** to catheter **600** until final release of device **105** is desired, at which time tether **635** is cut.

In another embodiment, catheter **600** includes a convex cap **640** at distal end **600B**. Convex cap **640** eases the translumenal travel of catheter **600** through a blood vessel or other constriction. In one example, cap **640** is hinged to catheter **600**, such as at sheath **607**, so that cap **640** opens outwardly from distal end **600B** when device **105** is pushed out of cavity **605**. In another example, cap **640** includes one or more deformable flaps that similarly open outwardly to allow device **105** to be advanced out from cavity **605** by pushing device **105** against cap **640**. In a further embodiment, cap **640** includes a material that is soluble in body fluids after a predetermined time period. In this embodiment, cap **640** dissolves after catheter **600** is translumenally guided to left ventricle **135** or other desired location. After cap **640** dissolves, device **105** is advanced longitudinally outward from cavity **605** at distal end **600B** of catheter **600**. In another embodiment of the invention, cap **640** is omitted such that cavity **605** is open to distal end **600B** of catheter **600** even during translumenal insertion.

In one example, catheter **600** is used to place device **105** in a heart chamber, such as left ventricle **135**. One such technique includes inserting catheter **600** into the patient **115**, such as via the subclavian artery. Catheter **600** is translumenally guided through the artery, through the left atrium, and through the mitral valve until its distal end **600B** is within left ventricle **135**. Progress of the catheter **600**, as it travels from the insertion point to the left ventricle **135**, is typically monitored on a display using fluoroscopy. This assists the physician in translumenally steering catheter **600** along the proper path to a desired location in left ventricle **135**. In the embodiment of device **105** illustrated in Figure **3A**, which includes a corkscrew stabilizer **312A**, sheath **607** and/or cap **640** prevents the sharp tip of corkscrew stabilizer **312A** from damaging the blood vessel while device **105** is being translumenally maneuvered through the blood vessel.

In one embodiment, placement catheter **600** has high torsional stability and is steerable. In this embodiment, sheath **607** and portions of catheter **600** near its distal end **600B** are substantially rigid. Catheter **600** is adapted for receiving, at its proximal end **600A**, a removable stylet that extends longitudinally along catheter **600**. The stylet extends approximately to (or slightly beyond) a distal end of coupling member **630**. A straight stylet is typically employed until distal end **600B** of catheter **600** enters heart **110**. Then, the straight stylet is removed from catheter **600** and a stylet having a curved or bent distal end is inserted in its place. By rotating the bent stylet as catheter **600** is advanced into heart **110**, the distal end **600B** of catheter **600** is directed to the desired location in left ventricle **135** or other heart chamber.

When device **105** is positioned at a desired location in left ventricle **135**, plunger **610** is advanced slightly so that corkscrew stabilizer **312A** protrudes outwardly from cavity **605** and contacts the heart wall in the interior of left ventricle **135**. Handle **625** is rotated which, in turn, rotates plunger **610** together with device **105**, such that corkscrew stabilizer **312A** is screwed into the heart wall to secure device **105** in position (e.g., at the apex of left ventricle **135** or other desired location). After securing device **105**, plunger **610** is advanced further. Plunger **610** is designed to open outwardly when it is extended outside of sheath **607**. As a result, pins **615** disengage from receptacles **620**, releasing the grip of plunger **610** on device **105**. Tether **635** is then cut (at proximal end

600A of catheter **600**) and removed, thereby releasing device **105**. Catheter **600** is then withdrawn from the subclavian artery.

Figure **7** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another embodiment of device **105** and an environment in which it is used. In Figure **7**, housing **300** of device **105** is substantially implanted within the myocardium at the interior wall of left ventricle **135** of heart **110**. The pressure transmitting catheter **315** portion of device **105** extends outwardly from housing **300** into left ventricle **135** for sensing blood pressure its distal tip **320**. In this embodiment, deformable stabilizer **312D** is integrated with a sharpened end of housing **300** so that housing **300** can be advanced into the heart wall. Then, the deformable stabilizer **312D** is expanded in a spring-like fashion to secure device **105** at the desired location. Device **105** is implanted using a placement catheter **600** as described with respect to Figure **6**. In one embodiment, housing **300** is designed to promote fibrous ingrowth, such as by properly preparing housing **300** with a coating and/or surface roughening, or by incorporating a mesh or fabric into the outer surface of housing **300**.

Figure **8** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another embodiment of device **105** that is capable of being implanted substantially within the interior wall of left ventricle **135** of heart **110**. In this embodiment, device **105** includes a helical anchor **800** surrounding a portion of device **105**. In one embodiment, anchor **800** includes a highly elastic metal such as, for example, a memory metal such as nitinol. A spring constant of anchor **800** is low enough to allow anchor **800** to conform to housing **300** of device **105** while torsional force is being applied to insert device **105** into the myocardial tissue **805** or other tissue. Upon release of this torsional force, anchor **800** deforms, such as, for example, by returning to its original shape. This results in the application of force to the surrounding myocardial tissue **805** for securing a portion of device **105** to the tissue. In one embodiment, more than one anchor **800** is included such as, for example, an anchor **800** at both proximal end **300A** and distal end **300B** of housing **300** of device **105**. In another embodiment, housing **300** of device **105** includes a head **810** portion at proximal end **300A**. Head **810** limits the advance of device **105** within

myocardial tissue **805**. This ensures that device **105** has access to the left ventricle **135** or other heart chamber to allow accurate blood pressure measurements in the heart chamber. This also reduces the risk of fibrous tissue growing over the pressure-sensitive portion of device **105**, such as pressure transmitting catheter **315**.

Figure **9** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another embodiment of device **105** that is capable of being implanted substantially within myocardial tissue **805**. In this embodiment, device **105** includes a substantially rigid helical metal coil (e.g., a titanium coil) anchor **800** surrounding a portion of housing **300** of device **105**. Anchor **800** has a profile similar to that of device **105**, as illustrated in Figure **9**. Upon application of a torsional force, anchor **800** screws into the heart wall. In another embodiment, more than one anchor **800** is included such as, for example, an anchor **800** at both proximal end **800A** and distal end **800B**.

Conclusion

The present system includes, among other things, a sensor device such as a pressure monitor. The sensor device is implantable in a heart chamber or elsewhere, and it wirelessly communicates sensor information therefrom. In one embodiment, an implantable pressure monitor provides less invasive chronic measurements of pressure, such as, by way of example, but not by way of limitation, measurements of left ventricular blood pressure. The implantable pressure monitor reduces the risk of obtaining such important measurements, enabling a physician to more accurately diagnose and treat serious heart conditions.

Though particular aspects of the system have been described in conjunction with its use in measuring left ventricular blood pressure, it is understood that the system can also be used for measuring pressure elsewhere. For example, but not by way of limitation, the system can also be used for measuring pressure in other heart chambers, blood vessels (e.g., pulmonary artery), body organs (e.g., the bladder, kidney, uterus), or body cavities (e.g., for intracranial, intraocular, or intrapleural pressure measurements). Moreover, though translumenal implantation has been described using a placement catheter, the present system also includes implantation using an endoscope, laparoscope,

or other minimally invasive or other surgical technique. In one example, the implantable sensor device is directed into a urinary bladder via the urethra. In one such embodiment, the implantable sensor device includes a stabilizer or other structure that expands following disposition in the bladder. As a result, the implantable sensor device is retained in the bladder without blocking flow to the urethra.

Though particular aspects of the system have been described in conjunction with its use in measuring pressure, it is understood that the system can also be used with an implantable sensor for sensing manifestations of other physical parameters such as, by way of example, but not by way of limitation, sensing blood gasses or other gasses (e.g., O_2, CO_2), pH, electrocardiograms, and blood glucose. In another example, the system is used in conjunction with ultrasonic measurements (e.g., measuring blood flow, or measuring heart wall thickness for determining contractility, etc.).

It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

WHAT IS CLAIMED IS:

1. An apparatus for sensing a parameter in a heart chamber in a heart in a living organism, the apparatus comprising:

a sensor, adapted for being disposed in the heart chamber, the sensor providing a sensor signal based on the parameter in the heart chamber; and

a wireless communication circuit, adapted for being disposed in the heart chamber, the communication circuit being coupled to the sensor and transmitting information out of the heart chamber based on the sensor signal.

2. The apparatus of claim **1**, in which the communication circuit is selected from the group consisting essentially of: a radio-telemetry circuit, a first inductance adapted for inductive coupling to a second inductance located outside the organ, a passive transponder, and an intracorporeal conductive communication device.

3. The apparatus of claim **1**, in which the sensor includes a pressure transducer.

4. The apparatus of claim **1**, further comprising:

a housing carrying the sensor and the communication circuit; and

at least one stabilizer that is coupled to the housing.

5. The apparatus of claim **4**, in which the stabilizer is adapted for securing the housing to a portion of the heart chamber, and the stabilizer is selected from the group consisting essentially of: a mesh that is adapted for receiving a growth of fibrous tissue from the heart chamber, a coating that is adapted for receiving a growth of fibrous tissue from the heart chamber, a corkscrew extending longitudinally from the housing, a helical anchor encompassing at least a portion of the housing, a harpoon, a threaded member, a hook, a barb, a fastener, and a suture.

6. The apparatus of claim **4**, in which the stabilizer includes a deformable member that is adapted for stabilizing the housing within the heart chamber.

7. The apparatus of claim **6**, in which the deformable member includes a memory metal.

8. The apparatus of claim **1**, further comprising:
a housing carrying the sensor and the communication circuit; and
a battery carried by the housing.

9. The method of claim **8**, in which the battery is rechargeable and further comprising an energy reception circuit coupled to the battery, the energy reception circuit adapted for receiving energy from outside the heart chamber for recharging the battery.

10. The apparatus of claim **1**, further comprising:
a housing carrying the sensor and the communication circuit; and
a signal processing circuit in the housing, the signal processing circuit being coupled to the sensor to receive the sensor signal, the signal processing circuit being coupled to the communication circuit to provide a signal-processed sensor signal to the communication circuit.

11. The apparatus of claim **1**, in which the heart chamber is selected from the group consisting essentially of a right atrium, a right ventricle, a left atrium, and a left ventricle.

12. The apparatus of claim **1**, further comprising a receiver, external to the heart chamber, that is communicatively coupled to the communication circuit for receiving the information based on the sensor signal.

13. The apparatus of claim **12**, in which the receiver is implanted in the living organism.

14. The apparatus of claim **12**, in which the receiver is external to the living organism.

15. The apparatus of claim **12**, further comprising a cardiac rhythm management device, implanted in the living organism and coupled to the receiver.

16. The apparatus of claim **12**, further comprising a computer that is communicatively coupled to the receiver for receiving the pressure information.

17. The apparatus of claim **12**, further comprising a cardiac rhythm management device, communicatively coupled to receive the information from the wireless communication circuit, the cardiac rhythm management device delivering therapy to the heart based on the sensor signal.

18. A cardiac rhythm management device, communicatively coupled to a plurality of the apparatuses of claim **1**.

19. A cardiac rhythm management device comprising:

a therapy circuit;

a leadwire coupled to the therapy circuit; and

an apparatus for sensing a parameter in a heart chamber in a heart in a living organism, the apparatus comprising:

a sensor, adapted for being disposed in the heart chamber, the sensor providing a sensor signal based on the parameter in the heart chamber; and

a wireless communication circuit, adapted for being disposed in the heart chamber, the communication circuit being coupled to the sensor and transmitting information out of the heart chamber based on the sensor signal.

20. An apparatus for measuring a pressure in a heart chamber, the apparatus comprising:

a pressure transducer, adapted for being disposed in the heart chamber, the pressure transducer providing a pressure signal based on the pressure in the heart chamber; and

a wireless communication circuit, adapted for being disposed in the heart chamber, the communication circuit being coupled to the pressure transducer and transmitting pressure information out of the heart chamber based on the pressure signal.

21. The apparatus of claim **20**, in which the heart chamber is selected from the group consisting essentially of a right atrium, a right ventricle, a left atrium, and a left ventricle.

22. An apparatus for measuring a blood pressure in a heart chamber in a heart in a living organism, the apparatus comprising:

a housing adapted for being disposed in the heart chamber;

a pressure transducer, adapted for being disposed in the heart chamber, the pressure transducer providing a pressure signal based on the blood pressure in the heart chamber;

a wireless communication circuit, carried by the housing and coupled to the pressure transducer, the communication circuit transmitting pressure information out of the heart chamber based on the pressure signal; and

at least one stabilizer, coupled to the housing, and adapted for stabilizing the housing within the heart chamber.

23. The apparatus of claim **22**, in which the communication circuit is selected from the group consisting essentially of: a radio-telemetry circuit, a first inductance adapted for inductive coupling to a second inductance located outside the organ, a passive transponder, and an intracorporeal conductive communication device.

24. The apparatus of claim **22**, further comprising a pressure transmission catheter adapted for receiving the pressure in the heart chamber, the pressure transmission catheter being coupled to the pressure transducer via a flowable

medium to communicate the pressure in the heart chamber to the pressure transducer.

25. The apparatus of claim **24**, in which the pressure transmission catheter includes a biocompatible gel-like tip that is adapted to receive the pressure in the heart chamber.

26. The apparatus of claim **22**, in which the pressure transducer includes a semiconductor resistive strain gauge.

27. The apparatus of claim **22**, in which the stabilizer is adapted for securing the housing to a portion of the heart chamber, and the stabilizer is selected from the group consisting essentially of: a mesh that is adapted for receiving a growth of fibrous tissue from the heart chamber, a coating that is adapted for receiving a growth of fibrous tissue from the heart chamber, a corkscrew extending longitudinally from the housing, a helical anchor encompassing at least a portion of the housing, a harpoon, a threaded member, a hook, a barb, a fastener, and a suture.

28. The apparatus of claim **22**, in which the stabilizer includes a deformable member that is adapted for stabilizing the housing within the heart chamber.

29. The apparatus of claim **28**, in which the deformable member includes a memory metal.

30. The apparatus of claim **22**, further comprising a battery that is carried by the housing.

31. The apparatus of claim **22**, further comprising a signal processing circuit in the housing, the signal processing circuit being coupled to the pressure transducer to receive the pressure signal, the signal processing circuit being coupled to the communication circuit to provide a signal-processed pressure signal to the communication circuit.

32. The apparatus of claim **22**, further comprising a receiver, external to the heart chamber, that is communicatively coupled to the communication circuit for receiving the pressure information.

33. The apparatus of claim **32**, in which the receiver is implanted in the living organism.

34. The apparatus of claim **32**, in which the receiver is external to the living organism.

35. The apparatus of claim **32**, further comprising a cardiac rhythm management device, implanted in the living organism and coupled to the receiver.

36. The apparatus of claim **32**, further comprising a computer that is communicatively coupled to the receiver for receiving the pressure information.

37. A method of sensing a parameter in a heart chamber in a heart in a living organism, the method comprising:

receiving a physical manifestation of the parameter in the heart chamber at a sensor device disposed within the heart chamber;

sensing, within the heart chamber, the physical manifestation of the parameter into a sensor signal; and

wirelessly communicating information, which is based on the sensor signal, from the heart.

38. The method of claim **39**, further comprising translumenally disposing the sensor device in the heart.

39. The method of claim **37**, in which communicating information includes radio-telemetering the information from the heart.

40. The method of claim **37**, in which communicating information includes inductively coupling the information from the heart.

41. The method of claim **37**, in which communicating information includes:

receiving energy from outside the heart at a passive transponder in the heart;

powering the passive transponder from the energy received from outside the heart; and

transmitting information from the heart using the powered passive transponder.

42. The method of claim **37**, further comprising:

receiving energy from outside the heart; and

recharging a battery located in the heart using the energy received from outside the heart.

43. The method of claim **37**, in which communicating information includes:

conducting a current through at least a portion of the living organism; and

receiving, at a receiver that is outside the heart chamber, a signal that is based on the current.

44. The method of claim **37**, in which communicating information includes:

conducting a current through at least a portion of the living organism; and

receiving, at a receiver that is external to the living organism, a signal that is based on the current.

45. The method of claim **37**, further comprising receiving the information at a receiver that is carried by an implantable medical device located within the living organism.

46. The method of claim **37**, further comprising:

receiving the information at a receiver that is external to the living organism; and

storing the information in a memory in the receiver.

47. The method of claim **46**, further comprising transferring the information from the receiver to a computer.

48. The method of claim **47**, further comprising analyzing the information in the computer.

49. The method of claim **48**, further comprising displaying to a user an indicator based on the information.

50. The method of claim **37**, in which the heart chamber is selected from a group consisting essentially of a right atrium, a right ventricle, a left atrium, and a left ventricle.

51. The method of claim **37**, further comprising receiving the information at a receiver that is carried by an cardiac rhythm management device located within the living organism.

52. The method of claim **51**, further comprising adjusting therapy delivered to the heart by the cardiac rhythm management device, wherein adjusting therapy is based on the sensor signal wirelessly communicated from the heart.

53. A method of measuring blood pressure in a heart chamber in a heart in a living organism, the method comprising:

receiving the blood pressure in the heart chamber at a pressure transducer device;

transducing, within the heart chamber, the blood pressure in the heart chamber into a pressure signal; and

wirelessly communicating blood pressure information, which is based on the pressure signal, from the heart.

54. The method of claim **53**, further comprising translumenally disposing the pressure transducer device in the heart via a placement catheter.

55. The method of claim **53**, in which receiving the blood pressure includes communicating the blood pressure from the heart chamber to the pressure transducer via a flowable medium.

56. The method of claim **55**, in which receiving the blood pressure includes receiving the blood pressure a distal end of a pressure transmission catheter and transmitting the blood pressure from the heart chamber to the pressure transducer via a flowable medium within the pressure transmission catheter.

57. The method of claim **56**, in which transducing the pressure includes:

receiving the blood pressure at the pressure transducer from the flowable medium within the pressure transmission catheter;

varying at least one resistance in the pressure transducer based on the received pressure; and

providing a resulting electrical signal, which includes pressure information based on the varying resistance of the pressure transducer.

58. The method of claim **53**, in which communicating pressure information includes radio-telemetering the pressure information from the heart.

59. The method of claim **53**, in which communicating pressure information includes inductively coupling the pressure information from the heart.

60. The method of claim **53**, in which communicating pressure information includes:

receiving energy from outside the heart at a passive transponder;

powering the passive transponder from the received energy from outside the heart; and

transmitting pressure information from the heart using the powered passive transponder.

61. The method of claim **53**, in which communicating pressure information includes:

conducting a current through at least a portion of the heart; and

receiving, at a receiver that is outside the heart, a signal that is based on the current.

62. The method of claim **53**, in which communicating pressure information includes:

conducting a current through at least a portion of the heart; and

receiving, at a receiver that is external to the living organism, a signal that is based on the current.

63. The method of claim **53**, further comprising:

translumenally disposing a pressure transducer device within the heart; and

stabilizing the pressure transducer device within the heart.

64. The method of claim **63**, in which stabilizing the pressure transducer device includes securing the pressure transducer device to the heart.

65. The method of claim **64**, in which securing the pressure transducer to the heart includes implanting the pressure transducer substantially within a wall of the heart.

66. The method of claim **53**, in which the heart chamber is selected from a group consisting essentially of a right atrium, a right ventricle, a left atrium, and a left ventricle.

67. The method of claim **53**, further comprising:

receiving the wirelessly communicated blood pressure information at a cardiac rhythm management device; and

adjusting therapy delivered to the heart by the cardiac rhythm management device based on the wirelessly communicated blood pressure information.

68. A method comprising:

inducing a current between first electrodes implanted in a living organism;

modulating the current at the first electrodes with a data signal; and

demodulating, at second electrodes, a signal based on the current.

69. The method of claim **68**, in which the second electrodes are implanted in the living organism.

70. The method of claim **68**, in which the second electrodes are external to the living organism.

71. A catheter comprising:

an elongate member having first and second ends, the first end of the elongate member including a cavity adapted for carrying an implantable measurement device that includes a wireless communication circuit, the elongate member also including a lumen extending substantially between the cavity and the second end of the elongate member; and

an engaging member, carried by the cavity and extendable outwardly from the cavity at the first end of the elongate member, the engaging member operatively coupled to a manipulator at the second end of the elongate member, the engaging member adapted for engaging the implantable measurement device.

72. The catheter of claim **71**, in which the elongate member is flexible and adapted for translumenal access to a heart chamber.

73. The catheter of claim **72**, further comprising a coupling member extending through the lumen between the engaging member and the manipulator

74. The catheter of claim **73**, further comprising a tether, adapted to be secured to the implantable measurement device, the tether extending substantially between the cavity and the manipulator.

75. The catheter of claim **71**, further comprising a convex cap coupled to the first end of the elongate member.

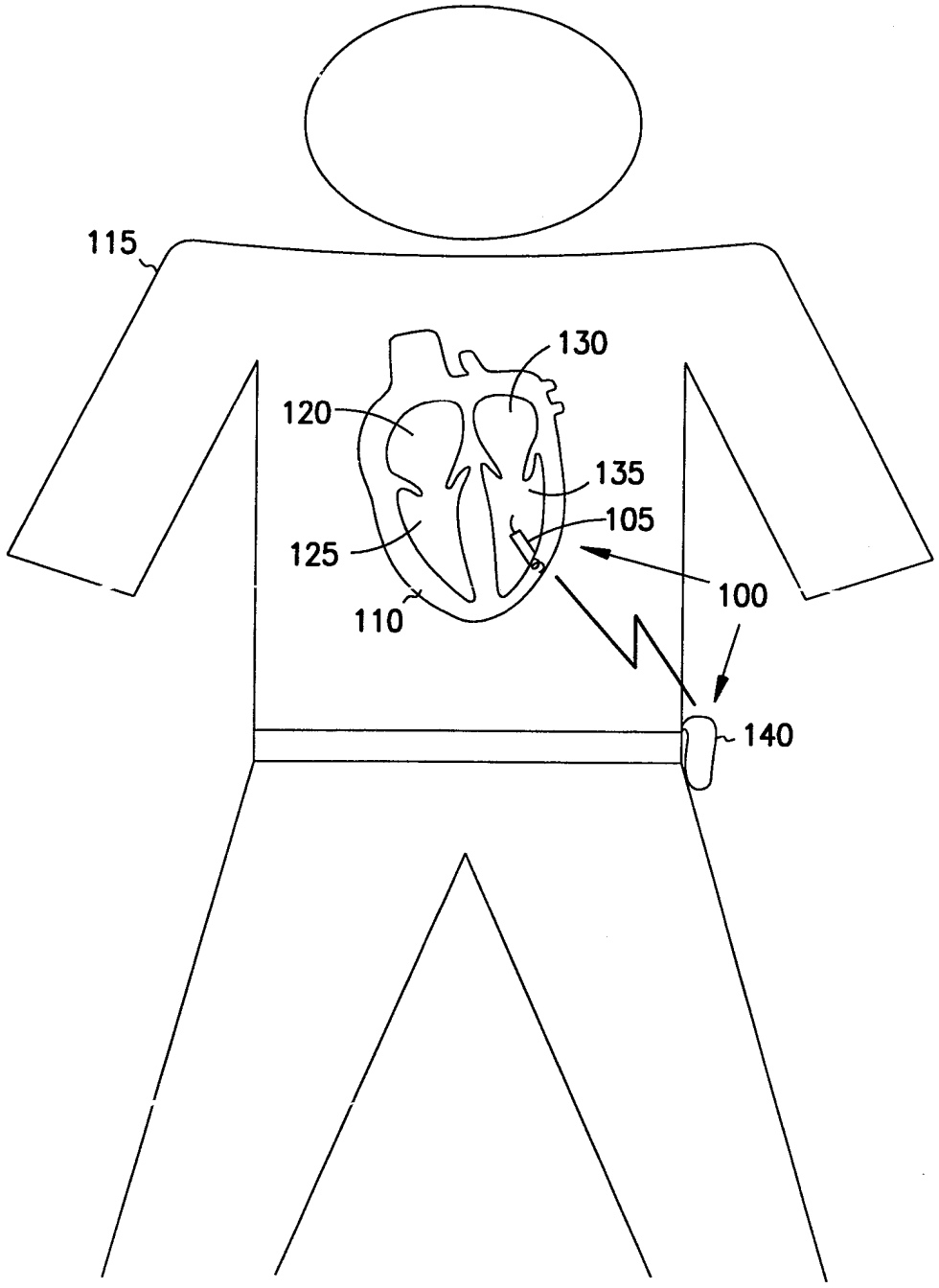


FIG. 1

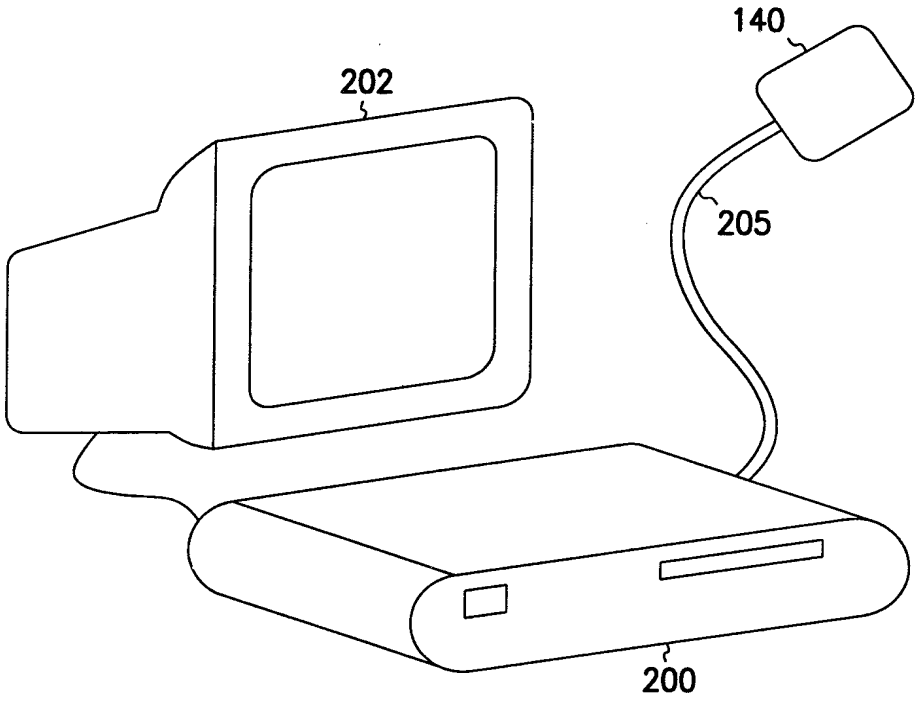


FIG. 2

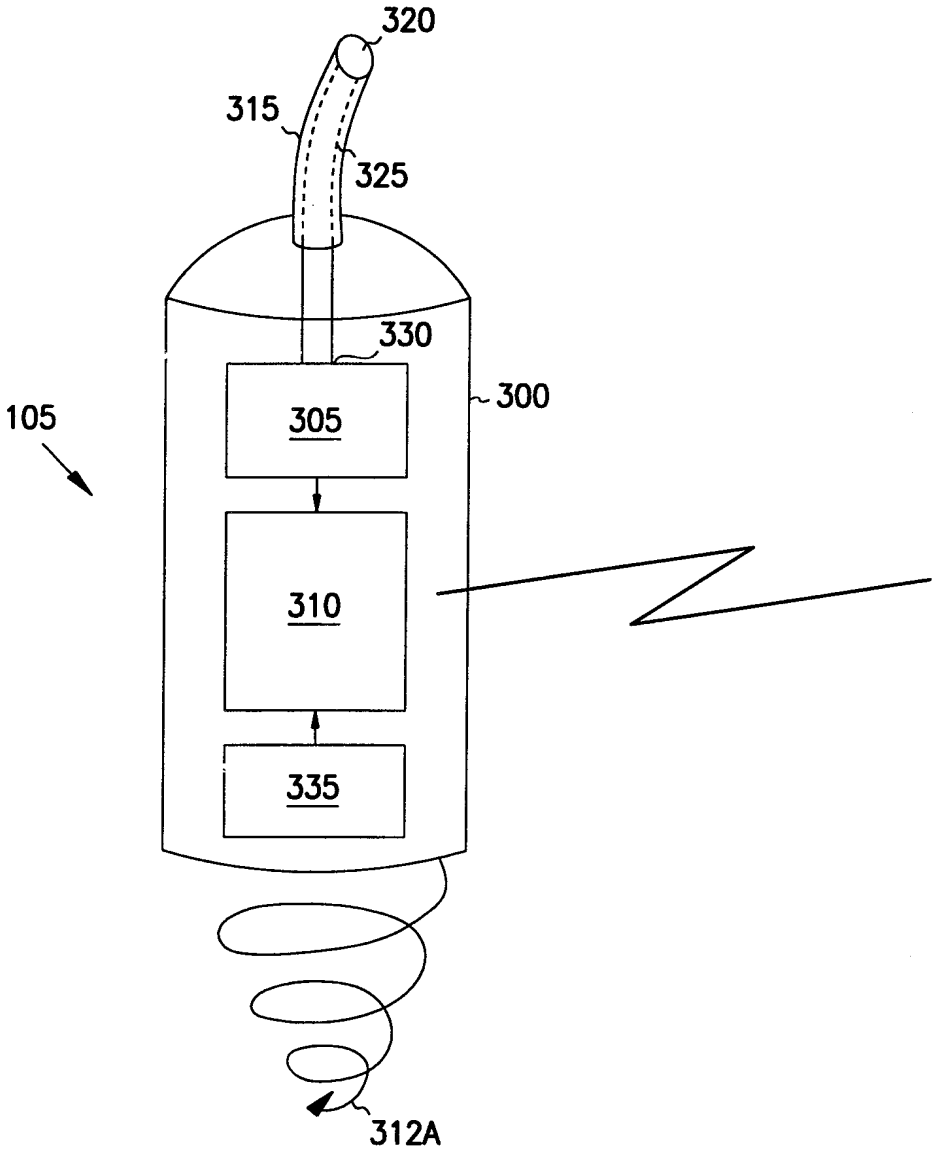


FIG. 3A

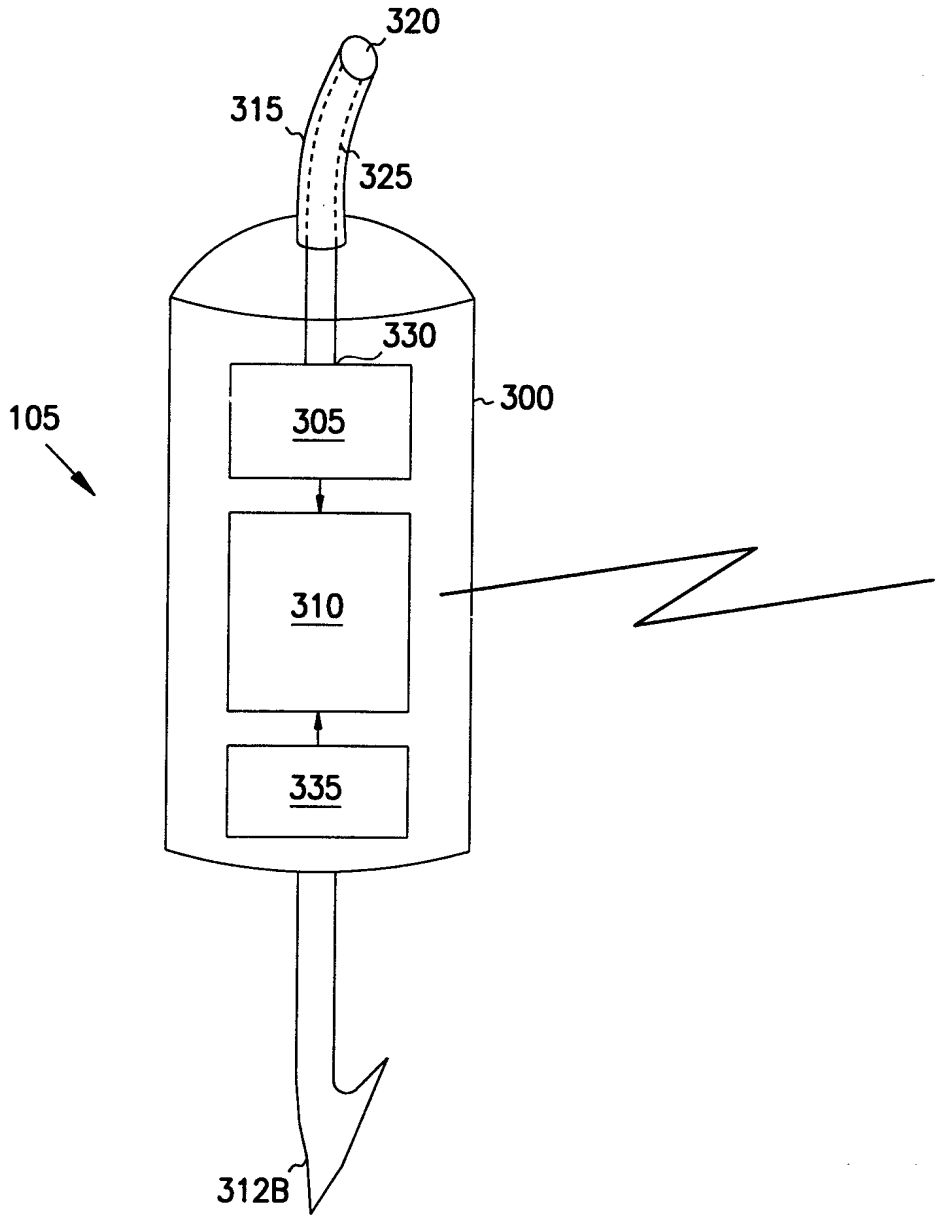


FIG. 3B

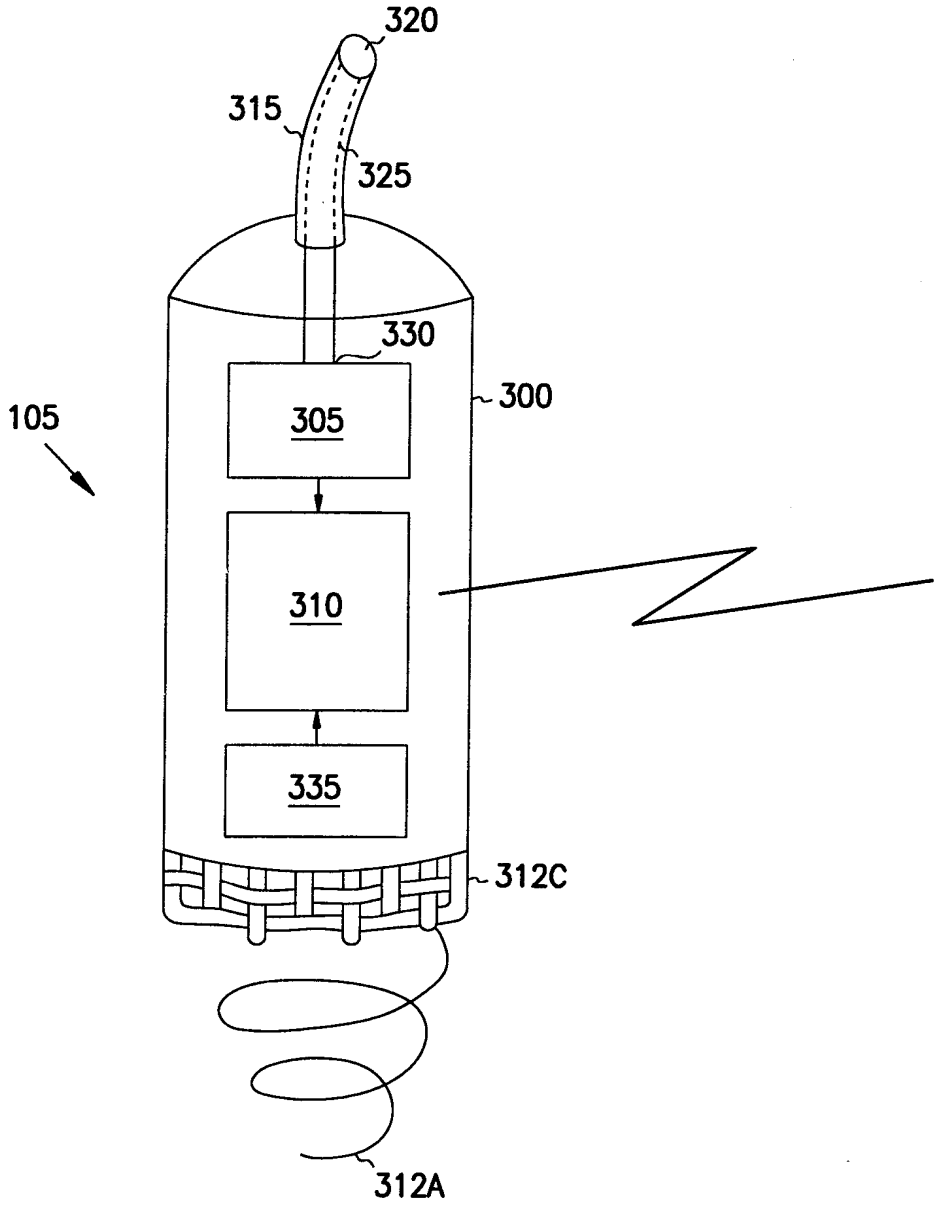


FIG. 3C

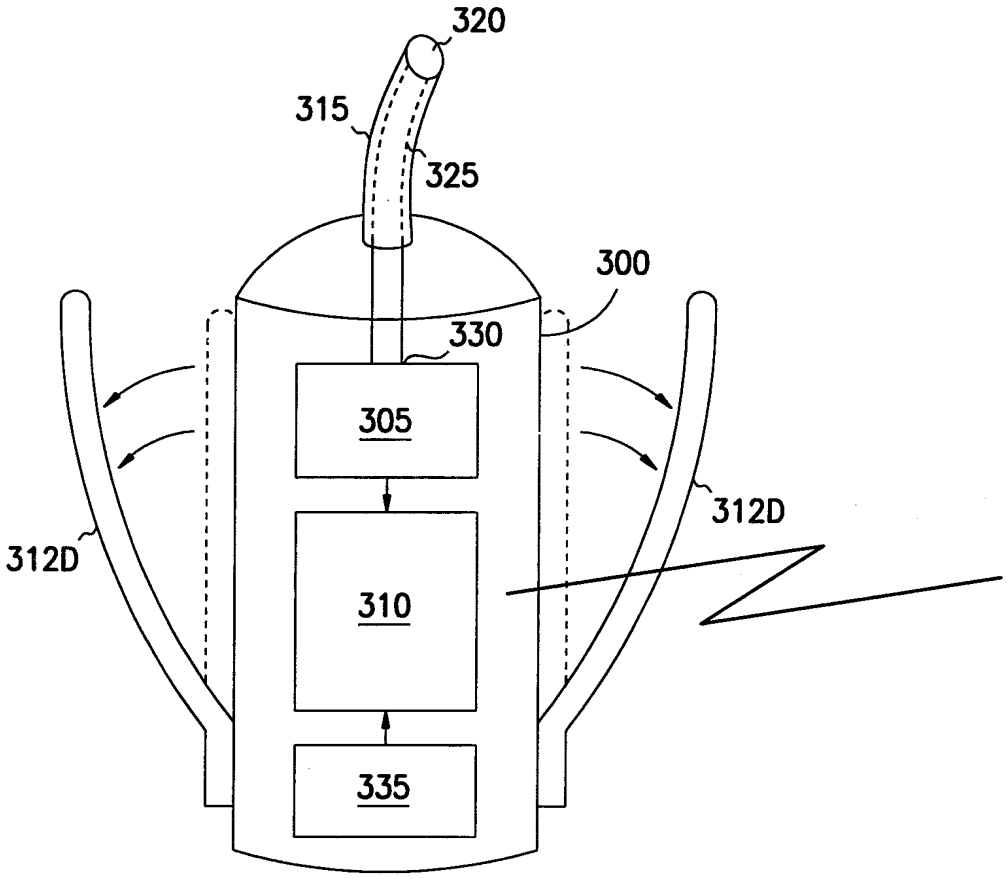


FIG. 3D

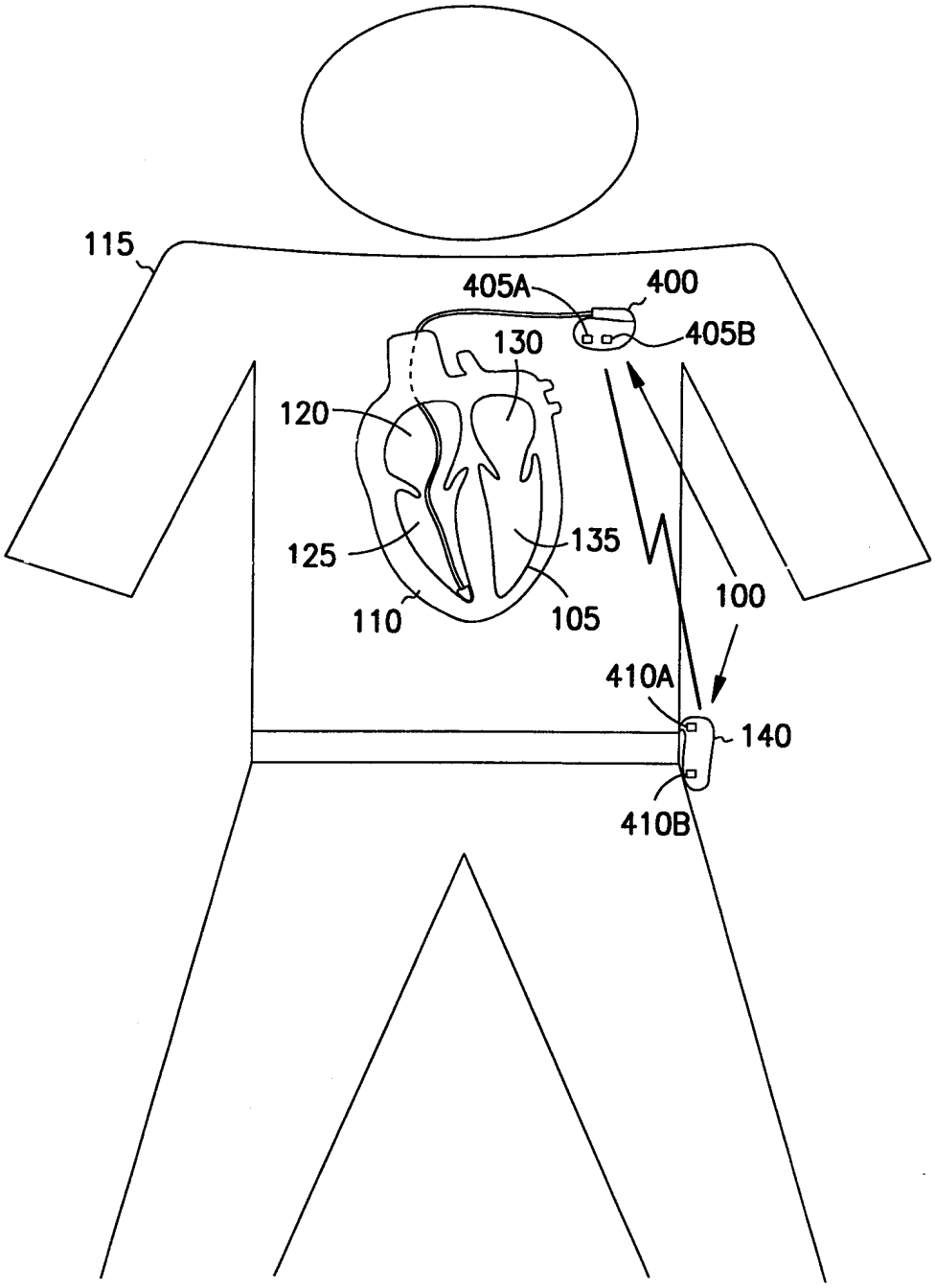


FIG. 4

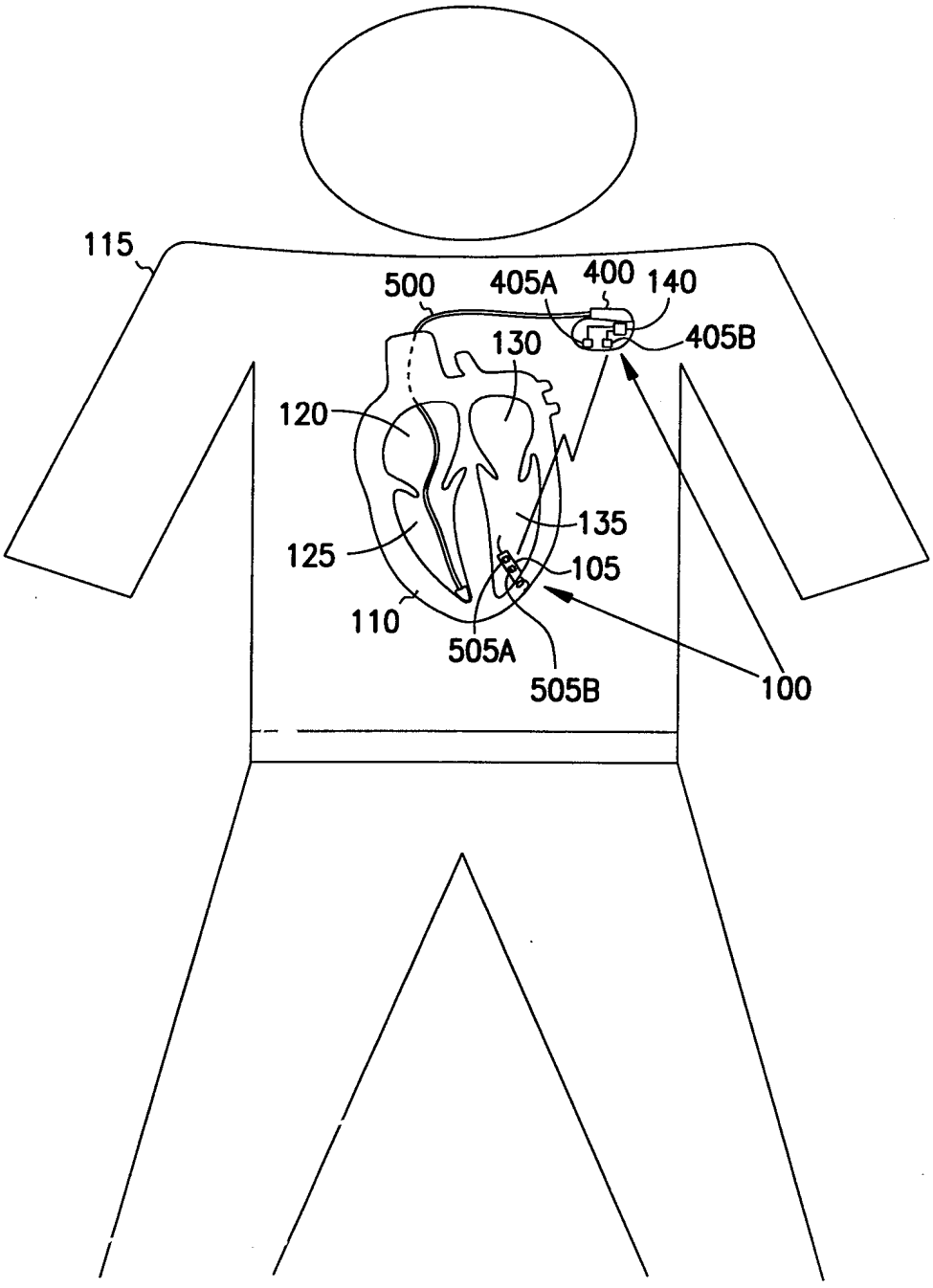
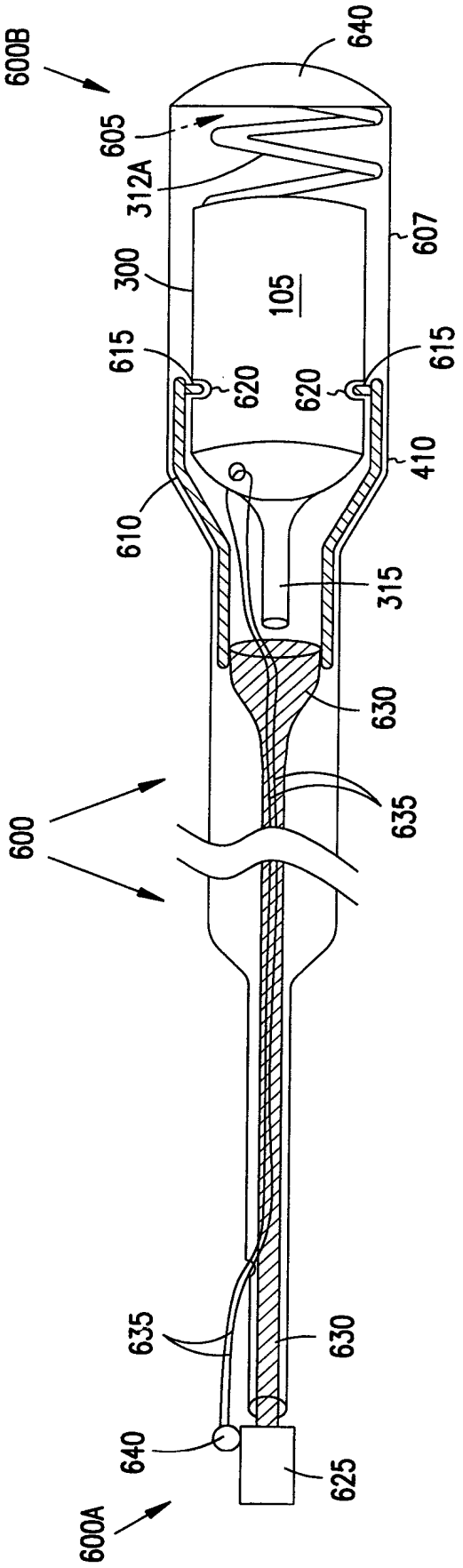


FIG. 5


600B
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625
600A

FIG. 6

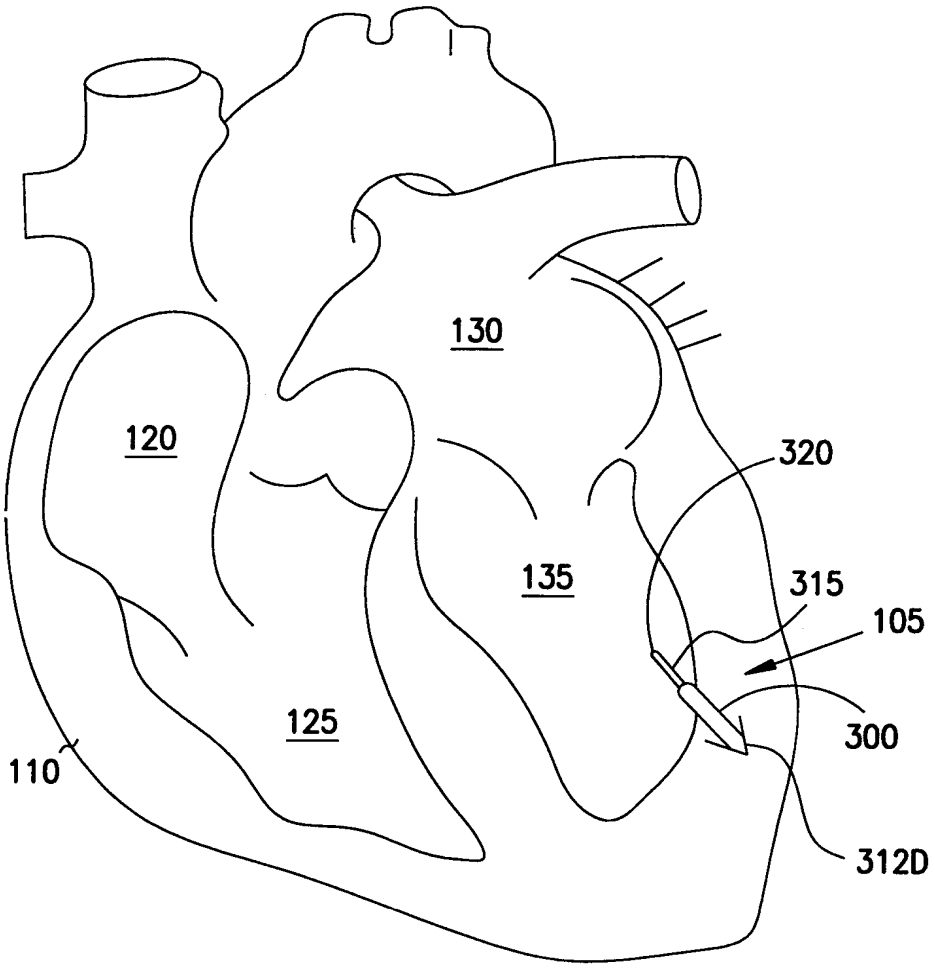

FIG. 7

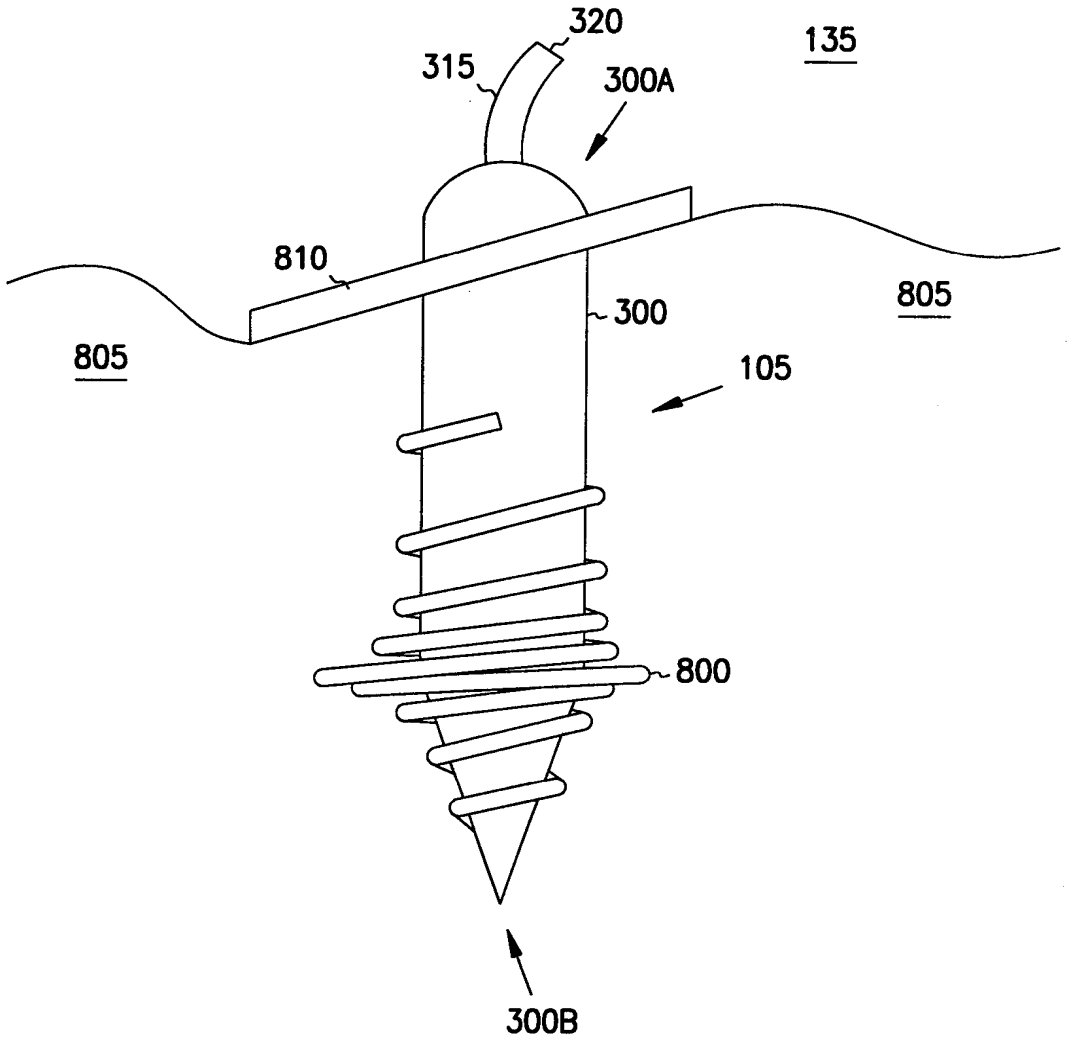

FIG. 8

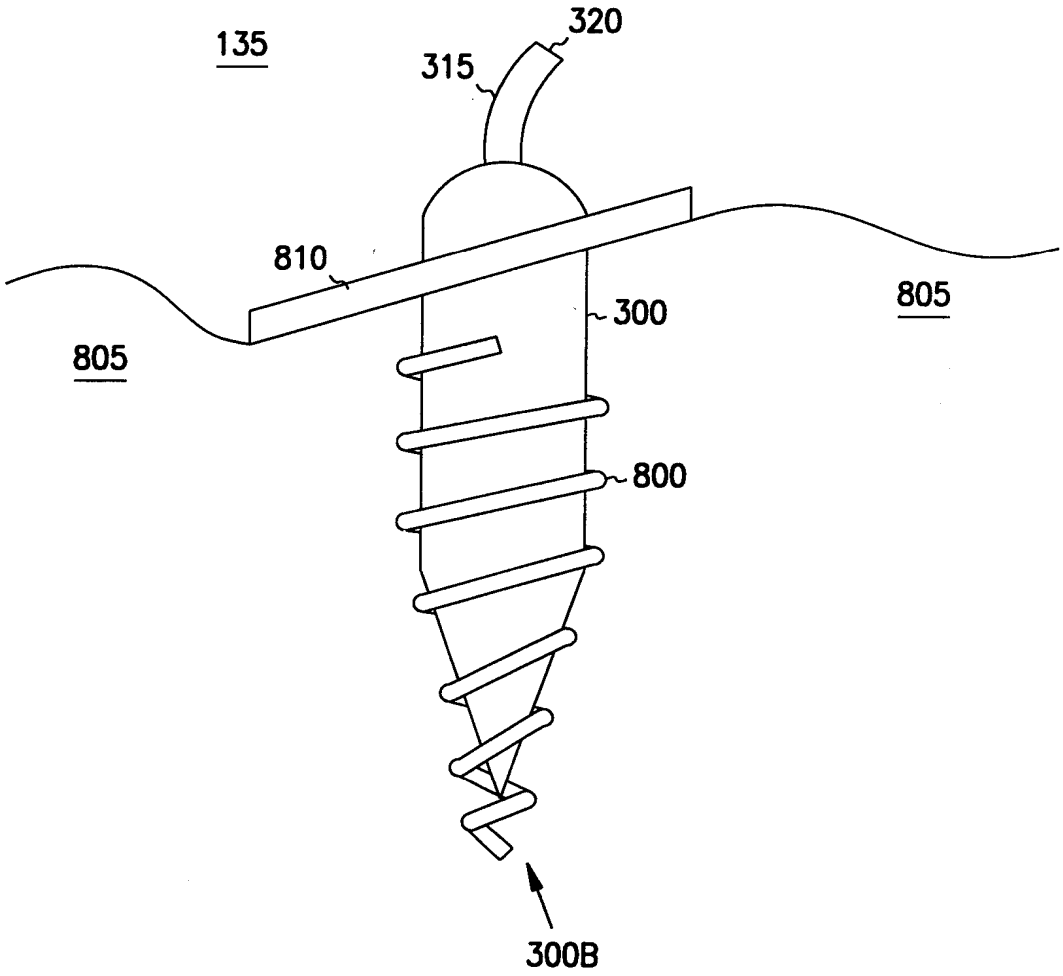

FIG. 9

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(71) Applicant: DATA SCIENCES INTERNATIONAL, INC. [US/US]; 4211 Lexington Avenue North, St. Paul, MN 55126 (US).

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(81) Designated States: CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

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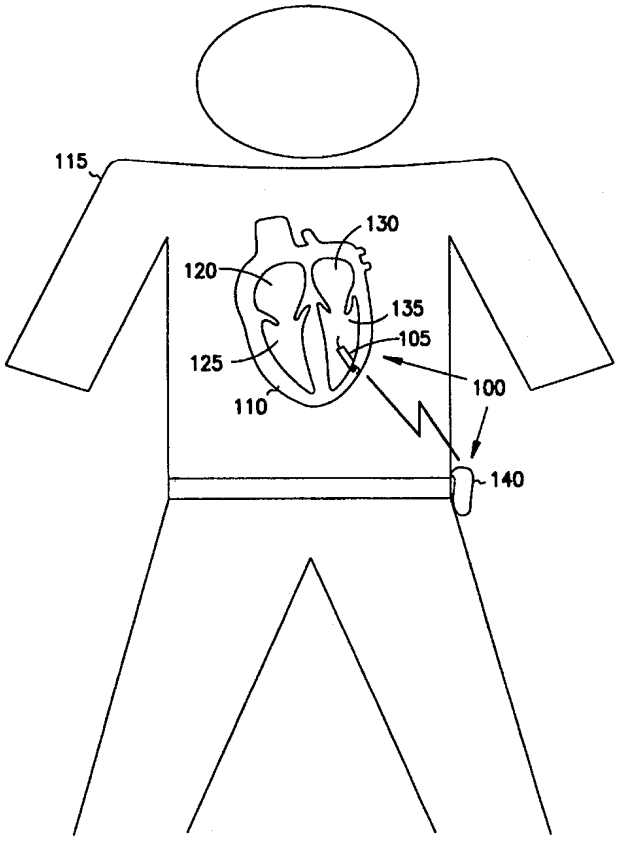
(54) Title: IMPLANTABLE SENSOR WITH WIRELESS COMMUNICATION

(57) Abstract

An implantable sensor device (105), such as a pressure monitor, is implanted in the left ventricle (LV) (135), in other heart chambers, or elsewhere, from which it wirelessly communicates pressure information to a remote communication device (140). The sensor device can be implanted using a placement catheter (600), an endoscope, or a laparoscope. The device can be secured entirely within the LV or heart wall, such as by using a corkscrew (312A), a helical anchor, a harpoon (312B), a threaded member, a hook, a barb, a fastener, a suture, or a mesh (312C) or coating for receiving fibrous tissue growth. The implantable sensor device (105) provides less invasive chronic measurements of left ventricular blood pressure or other physical parameters. The wireless communication techniques include radio-telemetry, inductive coupling, passive transponders, and using the body as a conductor (referred to as "intracorporeal conductive communication" or a "personal area network"). Data from the receiver is downloadable into a computer for analysis or display.



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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/20464

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 A61B5/0215

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61N A61M A01K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 487 760 A (VILLAFANA) 30 January 1996 (1996-01-30) column 3, line 24 -column 5, line 42 figures	1,19,37
A		2,4,8, 10-12, 14-18, 20-23, 27,28, 30,31, 34-36, 41,42, 46-48, 50-53, 58,60, 66,67

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 May 2000	21 06 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Chen, A

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/20464

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 97 33513 A (LIPOMATRIX INCORPORATED) 18 September 1997 (1997-09-18) abstract page 4, line 24 -page 6, line 7 page 11, line 30 -page 13, line 6 page 26, line 1 -page 29, line 10 page 35, line 9 - line 28 figures 1,7,9,12	1,20,22, 37,53
Y		71
A		2-5,8, 10,12, 14,19, 26,27, 31,32, 34,40, 41,59, 60,66

Y	US RE30366 E (RASOR ET AL.) 12 August 1980 (1980-08-12) column 3, line 55 -column 5, line 9 column 7, line 23 -column 8, line 11 figures 1-5C	71
A		72,73

X	US 4 494 950 A (FISCHELL) 22 January 1985 (1985-01-22) column 3, line 55 -column 5, line 50 figures 1,2	68
A		1,2, 8-10, 12-14, 37,39, 42,43, 45-49, 61,62, 69,70

X	US 4 987 897 A (FUNKE) 29 January 1991 (1991-01-29) column 6, line 4 -column 7, line 62 figure 1	68
A		70

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/20464

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	WO 95 33517 A (CUNNINGHAM) 14 December 1995 (1995-12-14) page 8, line 8 -page 10, line 4 page 12, line 27 -page 13, line 27 page 16, line 1 -page 18, line 8 page 29, line 18 -page 30, line 28 figures 1,19-21	1,2,4,5, 8,10-23, 27, 33-35, 37,39, 45,46, 51,52
A	US 4 846 191 A (BROCKWAY ET AL.) 11 July 1989 (1989-07-11) cited in the application column 5, line 8 -column 6, line 58 column 7, line 35 -column 8, line 12 figures 1-5	1-5,10, 12,14, 22-25, 27,31, 32,34, 53,55-58
A	US 4 913 147 A (FAHLSTROM ET AL.) 3 April 1990 (1990-04-03) column 6, line 53 -column 7, line 43 figures 16-25	5-7, 27-29
A	US 5 551 427 A (ALTMAN) 3 September 1996 (1996-09-03) column 9, line 52 -column 12, line 37 figures 7-12A	71-73
A	EP 0 337 035 A (CARDIAC PACEMAKERS, INC.) 18 October 1989 (1989-10-18) column 5, line 50 -column 7, line 17 figures 1-7	71-73,75

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/20464

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 38, 54 and 63-65
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery or therapy.
Method claims 38, 54 and 63-65 for sensing or measuring a parameter in a heart chamber comprising the surgical step of translumenally

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-37, 39-53, 55-62, 66 and 67

   Sensing a parameter in a heart chamber and transmitting information out of the heart chamber to a receiver.

2. Claims: 68-70

   Method of communicating signal data through a living body by inducing current in implanted electrodes.

3. Claims: 71-75

   Catheter for placing an implantable measurement device.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/20464

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5487760	A	30-01-1996	NONE		
WO 9733513	A	18-09-1997	US	5833603 A	10-11-1998
			AU	2401597 A	01-10-1997
			BR	9707974 A	27-07-1999
			CA	2248965 A	18-09-1997
			EP	0888079 A	07-01-1999
US RE30366	E	12-08-1980	US	3835864 A	17-09-1974
			CA	1003904 A	18-01-1977
			DE	2147308 A	23-03-1972
			FR	2107826 A	12-05-1972
			GB	1371034 A	23-10-1974
			GB	1371033 A	23-10-1974
			NL	7112915 A	23-03-1972
			SE	7410205 A	09-08-1974
			US	3943936 A	16-03-1976
US 4494950	A	22-01-1985	NONE		
US 4987897	A	29-01-1991	NONE		
WO 9533517	A	14-12-1995	AT	174228 T	15-12-1998
			AU	2626995 A	04-01-1996
			DE	69506544 D	21-01-1999
			DE	69506544 T	17-06-1999
			EP	0764038 A	26-03-1997
			ES	2127533 T	16-04-1999
US 4846191	A	11-07-1989	CA	1317482 A	11-05-1993
			DE	68923703 D	07-09-1995
			DE	68923703 T	04-04-1996
			EP	0417171 A	20-03-1991
			JP	2972251 B	08-11-1999
			JP	3504563 T	09-10-1991
			KR	130834 B	20-04-1998
			WO	8911244 A	30-11-1989
US 4913147	A	03-04-1990	DE	3783110 A	28-01-1993
			EP	0261582 A	30-03-1988
US 5551427	A	03-09-1996	NONE		
EP 337035	A	18-10-1989	CA	1326700 A	01-02-1994
			US	4827940 A	09-05-1989
			US	4876109 A	24-10-1989